COMPLETE® SE VASCULAR STENT SYSTEM

INSTRUCTIONS FOR USE

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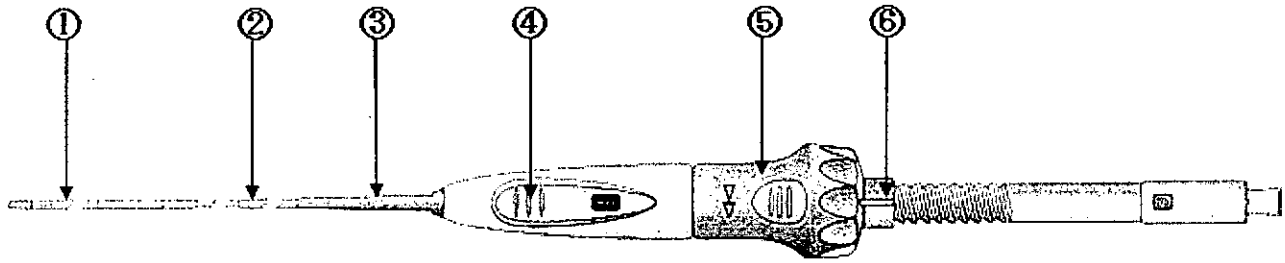
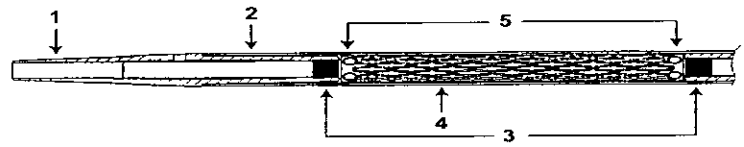
DEVICE DESCRIPTION

The Complete SE Vascular Stent System is intended to deliver a self-expanding stent to the Iliac arteries via a sheathed delivery system. The self-expanding stent is constructed of a nickel titanium alloy (Nitinol), and is compressed and loaded into the delivery system. The Complete SE Vascular Stent System (Figures 1 and 2) includes a pre-loaded self-expanding Nickel-Titanium alloy (Nitinol) stent with eight tantalum radiopaque markers (four on each end) (Figure 3) and an over-the-wire retractable sheath delivery system. The stent is delivered to the intended lesion site and then expanded by retraction of a protective sheath and remains as a permanent vessel scaffolding implant. Upon deployment, the stent imparts an outward radial force on the arterial lumen to establish patency.



1 Tip and Flexible Outer Member Sheath
2 Outer Stability Member
3 Strain Relief
4 Front Grip
5 Deployment Rotation/Slider Mechanism
6 Safety Lock

Figure 1: The Complete SE Vascular Stent Delivery System



1. Tip
2. Stent Sheath
3. Catheter Radiopaque Marker Bands
4. Stent
5. Tantalum Markers

Figure 2: Complete SE Vascular Stent Detail

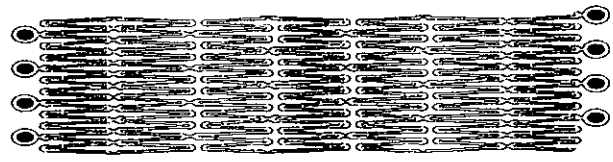


Figure 3: Complete SE Vascular Stent with Tantalum Markers

The stents are available in diameters of 6.0mm-10.0mm and lengths of 20mm-100mm (see Table 1).

Table 1: Complete SE Vascular Stent System Information

Unconstrained Stent Diameter (mm)	Stent Length (mm)	Minimum- Maximum Reference Vessel Diameter (mm)	Minimum Sheath I.D. (in)
6.0	20, 40, 60, 80, 100	4.5- 5.5	0.087"
7.0	20, 40, 60, 80, 100	5.6- 6.5	0.087"
8.0	20, 40, 60, 80, 100	6.6- 7.5	0.087"
9.0	20, 40, 60, 80	7.6- 8.5	0.087"
10.0	20, 40, 60, 80	8.6- 9.5	0.087"

The stent delivery system, as shown in Figure 1, is composed of a multi-tubular coaxial convertible system that is compatible with a 0.035" guidewire and a stabilizing member that facilitates ease of use during deployment. A selectable rotation and slide deployment handle with a safety lock allows for deployment of the stent. Radiopaque marker bands are located on both the distal and proximal sides of the self-expanding stent for correct anatomical placement (see Figure 2 and 3).

INDICATIONS FOR USE

The Medtronic Vascular Complete SE Vascular Stent System is indicated for improving luminal diameter in patients with iliac stenosis in previously unstented lesions with vessel reference diameters between 4.5 mm and 9.5 mm and lesion lengths up to 90 mm. The stent is intended as a permanent implant.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

1. The Complete SE Vascular Stent System is provided sterile for one procedure only. Do not re-sterilize. Use prior to the "Use By" date noted on the package.
2. Use of the Complete SE Vascular Stent System requires advanced iliac angioplasty technical skills. The following instructions provide technical guidance but do not obviate the need for adequate training prior to use of the device.
3. Do not use if the temperature indicator found on the inner pouch is changed from a gray square to a black square as this indicates the unconstrained stent diameter and stent release may be compromised.
4. Persons with known hypersensitivities to nitinol and or its components (e.g. nickel, titanium) may suffer an allergic reaction to the Complete SE Vascular Stent.
5. Maintain the delivery system parallel to the patient and as straight as possible during the procedure to prevent delivery system catheter kinking.
6. Do not deploy the stent if it is not optimal or appropriate for the vessel. The stent cannot be repositioned once deployed.
7. Care should be taken when stenting near a bifurcation, aneurysm or bypass graft.
8. Prior to stent deployment, utilize fluoroscopy to verify the stent has not been damaged or dislodged during positioning.
9. If unable to initiate stent release, remove the entire system from the patient and advance a new, previously unopened stent delivery system.

10. Once deployment is initiated, the stent cannot be recovered by the sheath. In the event of partial delivery of the stent, remove the entire delivery system from the patient. This may result in damage to the vessel wall requiring surgical intervention.
11. Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the deployed stent. If the target lesion is not completely stented, use additional Complete SE Vascular Stents as necessary to adequately treat the lesion.

Precautions

1. The Complete SE Vascular Stent System is intended for use by physicians familiar with iliac stenting techniques and the risks associated with stenting.
2. Thrombogenicity evaluations were conducted using a heparinized model. If your patient cannot be adequately anticoagulated, it is unknown whether thrombus formation may occur with this product.
3. The use of overlapping stents with the Complete SE Vascular Stent System has not been formally evaluated in a clinical trial.
4. Caution must be taken when crossing the stented area with ancillary equipment to avoid dislodgment of the stent.

System Handling and Stent Placement Precautions

1. Careful stent sizing is important, see Table 1 for available diameters and lengths.
2. In order to achieve optimum sizing as well as apposition of the stent to the vessel wall, using an "interference" fit, a stent should be selected at least 0.5 mm greater in diameter than the vessel. For example, a 6.0 mm stent should be selected to treat a 4.5-5.5 mm diameter vessel; a 7.0mm stent should be selected to treat a 5.6-6.5 mm diameter vessel. Consideration should also be given to the length of the lesion to be treated when selecting the stent length.
3. In-vitro modeling has predicted the Complete SE Vascular Stent foreshortens between 3% (for 6 mm diameter stents) and 7% (for 10 mm diameter stents).
4. The delivery system has a working length of either 80cm or 130cm and is compatible with 0.035" guidewires. See Table 1 for guiding catheter or sheath compatibility.
5. Store in a cool, dry, dark place.
6. Check the expiration date on the package. DO NOT use if the device has expired.
7. Inspect the sterile package before opening. DO NOT use if any defects are noted.
8. Check the temperature indicator on the pouch. DO NOT use if the temperature indicator has changed from a gray square to a black square.
9. This product is designed for single use only. DO NOT re-use or re-sterilize.

Post-Implant Precautions

1. Temporary pacemaker, atropine, and phenylephrine HCL should be available in case of bradycardia or asystole arising from effects of the procedure.
2. Use caution if crossing a deployed stent with adjunctive devices.

SUMMARY OF CLINICAL INVESTIGATIONS

Two clinical studies were conducted to support the safety and efficacy of the Complete SE Vascular Stent System. The Iliac Stenting in Stenotic Lesions with the Bridge SE Self-Expanding Stent Delivery System Registry (ISIS-SE) study enrolled 158 patients in the United States and established the safety and efficacy of treating stenotic iliac lesions with the Bridge SE Self-Expanding Stent (a precursor to the Complete SE Vascular Stent). The Complete SE Iliac Registry was a confirmatory study conducted inside the United States. NOTE: The Complete SE Vascular Stent System reflects slight modifications to both the stent and delivery systems. The modifications to the stent include the addition of 8 tantalum markers (4 on each side), and modifications to the stent cut pattern and crown connections. The modifications to the delivery system include a lower crossing profile, additional radiopaque markers, and a modified handle (rotating slider ring) and outer sheath. The modifications to the stent system were studied in the Complete SE Iliac Registry trial.

Iliac Stenting in Stenotic Lesions with the Bridge SE Self-Expanding Stent Delivery System Registry (ISIS-SE)

The ISIS-SE Registry was a prospective, multi-center, study designed to evaluate the safety and efficacy of the Medtronic Bridge SE Stent Delivery System for the treatment of symptomatic ischemic peripheral vascular disease due to iliac stenosis.

Patient Population

158 subjects were enrolled at 19 sites in the United States with a mean age of 66 years (range: 31-90 years), including 99 males (62.7%). Study subject demographics are summarized in Table 2 and baseline target lesion characteristics in Table 3.

Table 2: Demographics and Medical History (ITT Population)

Patient Characteristic	Result
Age (yr)	
Mean±SD (n)	66±11 (158)
Minimum, maximum	31, 90
Gender, n/N (%)[1]	
Male	99/158 (62.7%)
Female	59/158 (37.3%)
Medical history, n/N (%)[2]	
Diabetes mellitus	50/158 (31.6%)
Type I	4/158 (2.5%)
Dyslipidemia requiring medication	110/157 (70.1%)
History of hypertension	126/158 (79.7%)
Cigarette smoking	127/157 (80.9%)
Currently smoking	57/155 (36.8%)
Family history of premature atherosclerotic disease	40/92 (43.5%)
History of coronary artery disease	116/157 (73.9%)
Previous MI	43/150 (28.7%)
Previous coronary PTCA	51/151 (33.8%)
Previous CABG	43/157 (27.4%)
Previous peripheral vascular disease	156/158 (98.7%)
Previous PTA/stenting to target limb	8/158 (5.1%)

Previous aorta/peripheral bypass to target limb	1/158 (0.6%)

[1] Percentage based on number of patients enrolled.
[2] Percentage based on number of patients assessed for the related parameter.

Methods

Subjects underwent stent placement using standard procedures (according to the Instructions for Use) for percutaneous interventional procedures. Prior to the procedure, subjects were given an oral dose of 325mg aspirin. After catheter introduction, supplemental anti-coagulation was administered at the discretion of the Investigator. No more than 2 stents were to be used to treat the target lesion; additional stents were used only in the event of a bailout procedure.

Duplex scans and ankle brachial index (ABI) or pulse volume recording (PVR) measurements were completed within 30 days post-procedure. After hospital discharge, subjects had follow-up visits on Day 30 and at 9-12 months. In addition, subjects receiving Ticlid had a follow-up on Day 14 for laboratory evaluation (WBC with differential and platelet count). Ischemic testing and walking assessment were performed at Day 30 and at 9-12 months. Duplex scans and ABI or PVR measurements also were performed at the Day 30 visit (if not previously conducted pre-discharge) and at 9-12 months. Angiograms were performed at follow-up visits as needed. Four additional follow-up telephone assessments were to be conducted at 6-month intervals starting after the 9-12 month visit.

Table 3: Baseline Target Lesion Characteristics (ITT Population)

Parameter / Statistic	Result
Reference vessel diameter (mm)	
Mean±SD (n)	7.8±1.1 (165)
Minimum, maximum	4.8, 10.2
Lesion length (total) (mm)	
Mean±SD (n)	25.4±14.6 (164)
Minimum, maximum	5.1, 98.8
Lesion % stenosis (most severe)	
Mean±SD (n)[1]	62.5±14.1 (165)
Minimum, maximum	26.6, 100.0
Patients with single lesion stenting	151 (95.6%)
Patients with bilateral lesions stenting	7 (4.4%)
Lesion characteristics, n/N (%)[1]	
Eccentric	29/165 (17.6%)
Ulceration	14/165 (8.5%)
Calcification	39/155 (25.2%)
None / Mild	116/155 (74.8%)
Moderate	26/155 (16.8%)
Severe	13/155 (8.4%)
Thrombus present	4/165 (2.4%)
Dissection	24/123 (19.5%)
0	99/123 (80.5%)
A[2]	0/24 (0.0%)
B[2]	17/24 (70/8%)
C[2]	6/24 (25.0%)
D[2]	1/24 (4.2%)
E[2]	0/24 (0.0%)
F[2]	0/24 (0.0%)

1 Unless otherwise specified, percentages based on number of lesions that were attempted and had available data.

2 Percentage based on number of lesions with dissection.

Results

Safety

The primary safety endpoint was the major adverse clinical events (MACE), defined as peri-procedure death, target limb loss or tissue necrosis, and clinically-driven TLR (target lesion revascularization with percutaneous transluminal angioplasty [PTA] or ipsilateral iliac bypass graft) rate as measured through 12 months. The primary safety endpoint was the MACE rate at 9-12 months post procedure. The following hypotheses were established to test the MACE rate at 9-12 month in the test device, using exact confidence intervals (one-sided) at $\alpha = 0.05$, compared to a performance goal for iliac stenting derived from historical literature:

H_0: $P_t > 21\%$
H_A: $P_t \leq 21\%$

Where Pt was the observed 9-12 month MACE rate in ISIS-SE.

The subject-based MACE rate through 365 days, was 3.3% (5 of 150 subjects) for the intent to treat (ITT) population. The upper bound of the 1-sided 95% confidence interval on the MACE rate through 12 months was 6.9%. Since the upper limit of the 1-sided 95% confidence interval on the observed 9-12 month MACE rate did not exceed 21%, the device met the performance goal for safety.

No subject in the ITT population experienced a MACE through 30 days. No deaths were reported within 30 days post-procedure, nor were any deaths associated with a complication of the index procedure or the device.

Table 4: MACEs Through 12 Months: Adjudicated Events (ITT Population)

Event	Statistic n/N (%)[1]
Any MACE	5/150 (3.3%)
Death due to:	
Bleeding	0/150 (0.0%)
Vascular repair	0/150 (0.0%)
Transfusion reaction	0/150 (0.0%)
Bypass surgery	0/150 (0.0%)
Any death within 30 Days	0/150 (0.0%)
Target limb loss	1/150 (0.7%)
Target limb tissue necrosis	2/150 (1.3%)
Target lesion revascularization with PTA	2/150 (1.3%)
Target lesion revascularization with iliac bypass graft	1/150 (0.7%)

1 Based on number of patients enrolled with available data.

Efficacy

The primary efficacy endpoint was the 9-12 month patency rate, as measured by Duplex ultrasound (DUS). The following hypotheses were established to test the patency rate at 9-12 months in the test

device, using exact confidence intervals (one-sided) at $\alpha = 0.05$, compared to a performance goal for iliac stenting derived from historical literature:

H_0: $P_t > 18.5\%$
H_A: $P_t \leq 18.5\%$

Where Pt was the observed 9-12 month patency failure rate in ISIS-SE.

The primary efficacy endpoint, the 9-12 month patency rate as measured by color duplex ultrasound scan for the ITT evaluable population and the PP population was 100.0%. The upper bound of the one-sided 95% confidence interval on the patency failure rate through 9-12 months was 2.2% and 2.3% for the ITT evaluable and PP populations, respectively. Since the upper bound of the one-sided 95% confidence interval on the patency failure rate through 9-12 months did not exceed 18.5%, the device met the performance goal for effectiveness.

Additionally, acute clinical success as defined by device, lesion and procedural success (all of which required a residual stenosis of <30%) was 86.6% among subjects in the ITT population. See Table for the individual device, lesion, and procedure success rates.

Table 5: Acute Clinical Success (ITT Population)

Secondary Endpoint Parameter / Statistic	Result N=158 patients, N_b=166 lesions
Acute clinical success	
Device success, n/N_b (%)[1]	142/164 (86.6%)
Lesion success, n/N_b (%)[1]	144/164 (87.8%)
Procedure success, n/N (%)[2]	135/155 (87.1%)

N = Number of patients enrolled
N_b = Number of lesions as reported by Angiographic Core Laboratory
[1] Percentage based on number of lesions implanted for which data were available for the related parameter.
[2] Percentage based on number of patients enrolled for which data were available (for patients with bilateral stenting, the worse case was counted).

Summary of Adverse Events

An independent Clinical Events Committee (CEC) developed specific criteria for the categorization of clinical events and clinical endpoints in this study, including procedural death, vascular complications, target limb loss or tissue necrosis, and target lesion/vessel revascularization. Sites also reported study-specific serious adverse event (SAEs) related to the device and/or procedure. Study-specific SAEs included death, target limb loss, repeat percutaneous revascularization of the target lesion or vessel, iliac bypass surgery, major bleeding events requiring transfusion (within 30 days), and target limb tissue necrosis.

Adverse events through 12 months post-procedure are summarized by System Organ Class (SOC)

Table 6: Adverse Events Through 12 Months (ITT Population)

System Organ Class	Number of Patients n (n/N %)[1]
At least one adverse event	70
Blood and lymphatic system disorders	5 (3.2%)
Cardiac disorders	9 (5.7%)
Eye disorders	1 (0.6%)
Gastrointestinal disorders	3 (1.9%)
General disorders	1 (0.6%)
Infections	1 (0.6%)
Injury, poisoning and procedural complications	8 (5.1%)
Investigations	1 (0.6%)
Metabolism and nutritional disorders	1 (0.6%)
Musculoskeletal and connective tissue disorders	5 (3.2%)
Neoplasms, benign, malignant	5 (3.2%)
Nervous system disorders	2 (1.3%)
Psychiatric disorders	1 (0.6%)
Renal and urinary disorders	6 (3.8%)
Reproductive system disorders	1 (0.6%)
Respiratory, thoracic disorders	10 (6.3%)
Skin and subcutaneous tissue disorders	3 (1.9%)
Surgical and medical procedures	12 (7.6%)
Vascular disorders	35 (22.2%)

[1] Percentages based on number of patients enrolled (N=158).

The Medtronic Bridge SE Stent Delivery System was well tolerated among patients with symptomatic ischemic peripheral vascular disease due to iliac stenosis. Furthermore, the safety profile of the study device seen in this study was consistent with that reported in other clinical studies or registries of iliac stent systems.

The Complete SE Iliac Registry

The Complete SE Iliac Registry is ongoing; however, the primary endpoint for the 50 subject data was safety at 30 day as measured by the occurrence of major adverse events (MAE) defined as any death, target limb loss or clinically-driven TLR/TVR (target lesion revascularization/target vessel revascularization) with percutaneous transluminal angioplasty or aorto-iliac bypass graft for all subjects enrolled. Fifty-eight stents were delivered without complication in the first 50 subjects. No MAEs were reported through 30 days of follow-up.

The data for the first 50 subjects through 30 days of follow-up enrolled at 12 sites in the US are presented below.

Patient Population

Patients 18 years of age and older with symptomatic ischemic peripheral vascular disease having a stenotic lesion of ≥50% in the common or external iliac arteries or asymptomatic patients having a stenotic lesion of ≥70% in the common or external iliac arteries that were amenable to treatment by percutaneous stenting were eligible for this study. Multiple vessel disease, *de novo* target lesions, restenotic lesions that have not undergone any percutaneous interventional treatment using the same access site to any vessel within a minimum of 30 days prior to enrollment into the study were included. The minimum reference vessel diameter was between 4.5mm and 9.5mm and therefore appropriate for treatment with available stent diameters of 6.0mm to 10.0mm.

Table 7: Subject Demographic, Medical History and Risk Factors (ITT Population)

	ITT = 50
Age (year)	
Mean ± SD (n)	66 ± 12 (50)
Median	67
Min – Max	43 – 89
Gender	
Male % (n/N)	56.0% (28/50)
Female % (n/N)	44.0% (22/50)
Medical History and Risk Factors	
Diabetes Mellitus % (n/N)	34.0% (17/50)
Type I % (n/N)	2.0% (1/50)
Type II % (n/N)	28.0% (14/50)
Unknown % (n/N)	4.0% (2/50)
Dyslipidemia % (n/N)	84.0% (42/50)
Hypertension % (n/N)	90.0% (45/50)
Cigarette Smoking % (n/N)	86.0% (43/50)
Currently Smoking Cigarettes % (n/N)	48.0% (24/50)
History of Stroke or TIA % (n/N)	15.2% (7/46)
History of Coronary Artery Disease % (n/N)	69.4% (34/49)
Previous MI % (n/N)	43.3% (13/30)
Previous Peripheral Vascular Disease (other than iliac) % (n/N)	75.5% (37/49)
Previous PTA/Stenting to Target Limb % (n/N)	16.0% (8/50)
Previous Aorta/Peripheral Bypass to Target Limb % (n/N)	4.0% (2/50)

Note: Different denominators are due to missing data

Methods

After a series of screening assessments and administration of written informed consent, subjects underwent stent placement using standard procedures (according to the Instructions for Use) for percutaneous interventional procedures. After catheter introduction, supplemental anti-coagulation was administered at the discretion of the Investigator. No more than one stent was to be used to treat the target lesion(s); additional stents were used only in the event of a bailout procedure.

After hospital discharge, patients were required to return to the study center for clinical assessments on Day 30 ±5 days. Ischemic testing, duplex scans, ABI, toe brachial index (TBI), or PVR measurements, and walking assessment were performed at the Day 30 visit. Additionally, an angiogram was performed as needed to assess the safety and efficacy of the Complete SE Vascular Stent.

Table 8: Angiographic Morphology Data (ITT Population)

Lesion Characteristic	ITT = 50 Lesions as Angiographic Core Laboratory Reported = 55 % (n/N)[a]
Pre Procedure Assessment	
Lesion Pre Procedure Percent Stenosis (most severe)	
Mean ± SD (n)	72.5 ± 14.6 (55)
Median	69.6
Min – Max	51.3 - 100.0
Subjects with Single Limb Stenting	88.0% (44/50)
Subjects with Bilateral Limb Stenting	12.0% (6/50)
Eccentric	25.5% (14/55)
Ulceration	0.0% (0/55)
Calcification	32.7% (18/55)
None/mild	67.3% (37/55)
Moderate	20.0% (11/55)
Severe	12.7% (7/55)
Thrombus	0.0% (0/55)
Post Procedure Assessment	
Dissection	
0	94.5% (52/55)
A	0.0% (0/55)
B	3.6% (2/55)
C	1.8% (1/55)
D	0.0% (0/55)
E	0.0% (0/55)
F	0.0% (0/55)

[a] Percentage is based on the number of lesions attempted and for which data were available.

Results

There were no MAEs in the first 50 subjects followed from enrollment through the 30-Day Follow-Up Visit.

Table 9: Primary Endpoint and Details of Major Adverse Events through 30-Day (ITT Population)

	ITT = 50	
Major Adverse Events	**% (n/N)[a]**	**Exact 95% CI**
Any Major Adverse Event	0.0% (0/50)	(0.0%, 7.1%)
Any Death	0.0% (0/50)	(0.0%, 7.1%)
Target Limb Loss	0.0% (0/50)	(0.0%, 7.1%)
Target Lesion Revascularization (TLR)	0.0% (0/50)	(0.0%, 7.1%)
TLR by Percutaneous Transluminal Angioplasty (PTA)	0.0% (0/50)	(0.0%, 7.1%)
TLR by Iliac Bypass Graft	0.0% (0/50)	(0.0%, 7.1%)
Target Vessel Revascularization (TVR)	0.0% (0/50)	(0.0%, 7.1%)
TVR by PTA	0.0% (0/50)	(0.0%, 7.1%)
TVR by Iliac Bypass Graft	0.0% (0/50)	(0.0%, 7.1%)

[a] Percentage based on number of evaluable subjects for MAE.

In addition, the results for the endpoints of acute, clinical and hemodynamic success are 89.8%, 85.2% and 100% respectively.

Table 10: Secondary Endpoints (ITT Population)

	ITT = 50 Lesions as Site Reported =56	
Secondary Endpoints	**% (n/N)[a]**	**Exact 95% CI**
Acute Success[b]	89.8% (44/49)	(77.8%, 96.6%)
Clinical Success at 30-Day[c]	85.2% (46/54)	(72.9%, 93.4%)
Hemodynamic Success at 30-Day[d]	100.0% (55/55)	(93.5%, 100.0%)

[a] Percentage based on number of lesions implanted and had available data (acute success on subject level)

[b] Acute success defined as Angiographic evidence of <30 % final residual stenosis of the target lesion after stent placement and no occurrence of a device- related or procedure-related MAE or vascular event (stent thrombosis, major bleeding complications, etc.) prior to hospital discharge for all subjects enrolled into the registry

[c] Clinical success an improvement of the Rutherford scale by ≥1 category between pre-procedure (baseline) and the scheduled follow-up visits

[d] Hemodynamic success an improvement in ankle-brachial Index (ABI) or toe-brachial index (TBI)>0.10 over pre-procedure level OR deterioration of ≤ 0.15 from first post-procedure exam **OR** pulse volume recording (PVR) distal to the target lesion treated maintained at ≥5 mm above pre-procedure tracing for those subjects with no pre-procedure ABI/TBI (Note: Site, CEC and Angiographic Core Laboratory Reported Table)

Summary of Adverse Events

An independent Clinical Events Committee (CEC) developed specific criteria for the categorization of clinical events and clinical endpoints in this study. The specific criteria related to death, target limb loss, and target lesion/vessel revascularization. Sites also reported study-specific serious adverse event (SAEs) related to the device and/or procedure.

Table 11: Adverse Events

	ITT = 50 Total Adverse Events = 42 Subjects with at Least one Adverse Event = 15
System Organ Class	**Number of Subjects % (n/N)[a]**
Blood and Lymphatic System Disorders	2.0% (1/50)
Cardiac Disorders	8.0% (4/50)
Gastrointestinal Disorders	6.0% (3/50)

	ITT = 50 Total Adverse Events = 42 Subjects with at Least one Adverse Event = 15
General Disorders and Administration Site Conditions	2.0% (1/50)
Hepatobiliary Disorders	2.0% (1/50)
Infections and Infestations	2.0% (1/50)
Injury, Poisoning and Procedural Complications	2.0% (1/50)
Musculoskeletal and Connective Tissue Disorders	10.0% (5/50)
Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)	2.0% (1/50)
Nervous System Disorders	4.0% (2/50)
Psychiatric Disorders	2.0% (1/50)
Renal and Urinary Disorders	2.0% (1/50)
Respiratory, Thoracic and Mediastinal Disorders	6.0% (3/50)
Skin and Subcutaneous Tissue Disorders	6.0% (3/50)
Vascular Disorders	10.0% (5/50)

[a] Percentage based on total number of subjects in ITT population

Overall, the data demonstrated an acceptable safety profile (0.0% MAE Rate) of the Complete SE Vascular Stent Delivery System for the treatment of *de novo* and restenotic lesions in the iliac arteries in subjects with peripheral vascular disease.

Potential Complications

The following complications may be associated with the use of iliac stenting devices or iliac angioplasty:

- Abrupt stent closure
- Allergic reaction (contrast medium; drug; stent or filter material)
- Amputation/limb loss
- Aneurysm or pseudoaneurysm in vessel or at vascular access site
- Angina/ Coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial and/or ventricular tachycardia, atrial and/or ventricular fibrillation [VF])
- Asystole or bradycardia requiring placement of a temporary pacemaker
- Arteriovenous fistula
- Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- Death
- Detachment and/or implantation of a component of the system
- Emboli, distal (air, tissue, plaque, thrombotic material, stent)
- Fever
- Hematoma at vascular access site, with or without surgical repair
- Hemorrhagic event, with or without transfusion
- Hypotension/hypertension
- Infection, local or systemic including bacteremia or septicemia
- Ischemia requiring intervention (bypass or amputation of toe, foot, or leg)
- Myocardial infarction
- Pain (leg/foot)
- Pain at catheter insertion site
- Pulmonary embolism

- Renal failure/ insufficiency secondary to contrast medium
- Stent malposition/ migration
- Stent strut fracture
- Stroke
- Vascular thrombosis/ occlusion at puncture site, treatment site, or remote site
- Vessel dissection, perforation or rupture
- Vessel spasm or recoil
- Worsened claudication/rest pain

DIRECTIONS FOR USE

Preparation of Stent Delivery System

The delivery system has a working length of either 80cm or 130cm and is compatible with 0.035" guidewires. See Table 1 for guiding catheter or sheath compatibility.

1. Check the expiration date on the package. **Do not use if the device has expired.**
2. Inspect the sterile package before opening. **Do not use if any defects are noted.**
3. Check the temperature indicator on the pouch. **Do not use if the temperature indicator has changed from a gray square to a black square.**
4. Visually inspect the device

Patient Preparation

1. Administration of anticoagulant therapy pre- and post-procedure in accordance with standard industry practice is recommended and left to the discretion of the treating physician.
2. Temporary pacemaker, atropine, and phenylephrine HCL should be available in case of bradycardia or asystole arising from effects of the procedure.

Deployment Procedure

1. Under local anesthesia, prepare the vascular access site according to standard PTA procedures.
2. If not already done, perform baseline angiograms of both iliac arteries in the views that optimize visualization of artery to be treated.
3. At the discretion of the treating physician, pre-dilatation of the lesion can be performed using standard PTA techniques.
4. Using sterile technique, remove the Complete SE Vascular Stent System from packaging and inspect the distal end of the catheter to verify that stent has not been inadvertently deployed. No stent segments should be visible outside the catheter.

   NOTE: Do not remove the red safety lock (figure 4-4 below) on the system until the stent is positioned across the target lesion.

5. Flush the inner lumen with heparinized saline immediately before use. Do not use the delivery system if the saline flush is not observed exiting at the distal end of the catheter.

6. Insert the delivery system through the hemostatic valve adapter.
7. Carefully tighten the hemostatic valve adapter over the catheter outer member and ensure that the hemostatic valve adapter does not clamp down tightly on the outer sheath and impede its movement.

CAUTION: Do not over-tighten the hemostatic valve adapter.

8. After obtaining a road map image, advance the delivery catheter over the immobilized guidewire.
9. Maintain the delivery system parallel to the patient and as straight as possible during the procedure to prevent delivery system catheter kinking.
10. Using fluoroscopy, advance and position the stent across the lesion using distal and proximal marker bands and overall device radiopacity to visualize the correct placement.
11. Do not deploy the stent if it is not optimal or appropriate for the vessel. The stent cannot be repositioned once deployed.
12. Referring to Figure 4, remove the stent release mechanism on the delivery handle by releasing the red safety lock (Figure 4-4). Remove the red safety lock by firmly holding the handle (figure 4-1) while pushing the safety lock tab (Figure 4-5) to one side with the thumb. Once the safety lock tab is removed (Figure 4-4), recheck for proper position of the stent. Deployment is initiated by rotating the deployment rotation/slider mechanism in the direction of the arrows (Figure 4-2). After the first two or three segments are deployed and apposed to the vessel wall, the stent can be fully deployed by simultaneously squeezing the two deployments buttons (Figure 4-3) and gently pulling the release mechanism towards the end of the handle.
13. If unable to initiate stent release, remove the entire system from the patient and advance a new, previously unopened stent delivery system.

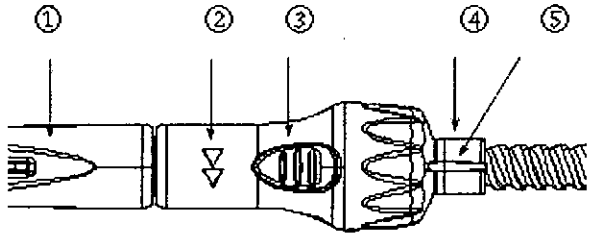


Figure 4: COMPLETE SE Vascular Stent System Deployment Handle Detail

NOTE: Keep the stent delivery catheter stationary during deployment. Do not hold the outer sheath of the delivery catheter during deployment as it must be free to move.

NOTE: Once deployment is initiated, the stent cannot be recovered by the sheath. If unable to initiate stent release, remove the entire system from the patient and advance a new, previously unopened stent delivery system.

NOTE: In the event of partial delivery of the stent, remove the entire delivery system from the patient. This may result in damage to the vessel wall requiring surgical intervention.

14. Under fluoroscopy, confirm that the stent has been deployed at the target lesion and is fully expanded.
15. In the event the self-expanding stent does not cover or partially covers the lesion, use an additional Complete SE Vascular Stent to adequately treat the lesion.

Device Removal Procedure

1. Leaving the guidewire in place, slowly remove the delivery catheter from the patient and discard the delivery system.
2. If additional stent-to-wall apposition is desired post-dilitation may be performed. Choose a balloon catheter matched to the diameter of the vessel and no larger than the expanded stent diameter. Dilate as needed in accordance with the compliance chart accompanying the selected balloon catheter.
3. Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.
4. Prior to completion of the procedure, view placement through fluoroscopy to ensure proper positioning of the deployed self-expanding stent.
5. Suspension of anticoagulant therapy post-procedure and removal of the introducer sheath should be performed per institutional protocol.
6. Seal the access site puncture per institutional protocol.

Post Stent Placement

1. Observation of the patient and fluoroscopy evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement.
2. Physician experience and discretion will determine the appropriate post-procedure observation and drug regimen for each patient.
3. Subsequent restenosis may require repeat dilatation of the vessel containing the stent. Crossing a stent with an adjunct device must be performed with caution.
4. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted

PATIENT INFORMATION

In addition to these Instructions for Use, the Complete SE Vascular Stent System is packaged with a Patient Implant Card for the patient that contains specific information about the Complete SE Vascular Stent. All patients should keep this card in their possession at all times for the procedure/ stent identification.

MRI COMPATABILITY

Non-clinical testing has demonstrated the Complete SE Vascular Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 and 3 Tesla
- Spatial gradient magnetic field of 720-Gauss/cm or less

- Maximum whole body averaged specific absorption rate (SAR) of 3.7 W/kg and 3.0 W/kg or less at 1.5 Tesla and 3 Tesla respectively, for 15 minutes of scanning

MRI-Related Temperature Rise
1.5-Tesla: In non-clinical testing, the Complete SE Vascular Stent produced a maximum temperature rise of 1.4 °C at a maximum whole body averaged specific absorption rate (SAR) of 3.7 W/kg, as assessed by calorimetry (calorimetry value of 1.54-W/kg) for 15 minutes of MR scanning in a 1.5-Tesla (1.5-Tesla/64-MHz, Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS) MR scanner. The effect of heating in the MRI environment for overlapping stents or stents with fractured struts is not known.
3-Tesla: In non-clinical testing, the Complete SE Vascular Stent produced a maximum temperature rise of 1.8 °C at a maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg, as assessed by calorimetry (calorimetry value of 2.8-W/kg) for 15 minutes of MR scanning in a 3.0-Tesla (3-Tesla/128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR scanner. The effect of heating in the MRI environment for overlapping stents or stents with fractured struts is not known.

Image Artifact

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Complete SE Vascular Stent. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

HOW SUPPLIED

Contents: One (1) sterile Complete SE Vascular Stent with Over-the-Wire (OTW) Delivery System.

Sterile: This device is sterilized with electron beam radiation. Non-pyrogenic.

Storage: Store in a dry, dark, cool place.

Protected by the following United States Patents: 6,306,141; 5,906,619; 6,911,039; and 7,105,016. Additional patents pending in the United States as well as other countries.

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